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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/693,121	10/20/2000	Jeffrey Schlom	45394	7805

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EXAMINER
YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 12/18/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/693,121	Applicant(s) SCHLOM ET AL.	
	Examiner Christopher H Yaen	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *30Days* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10-20-2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-15* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3, 6-10 are drawn to a method of generating an immune response to PSA by introducing a pox viral vector containing DNA encoding PSA linked to a promoter; contacting host with additional PSA or cytotoxic T-cell eliciting epitope; contacting host with an additional pox virus vector containing DNA encoding PSA linked to a promoter, using pox viruses of the suipox, avipox, capripox, and orthopox groups; and eliciting an immune response using PSA or T-cell eliciting epitope formulated with a either an adjuvant or liposomal formulation classified in class 514, subclass 44.

II. Claims 4-10, are drawn to a method of generating an immune response to PSA in a host by contacting host with PSA or a cytoptoic T-cell eliciting epitope followed by contacting with additional PSA encoded by a pox virus vector; using pox viruses of the suipox, avipox, capripox, and orthopox groups, and eliciting an immune response using PSA or T-cell eliciting epitope formulated with a either an adjuvant or liposomal formulation classified in class 514, subclass 44.

III. Claim 13, is drawn to a method of generating an immune response to PSA by contacting host with cytotoxic T-cell eliciting epitope of PSA, classified in class 424, subclass 198.1.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I-III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions relate as methods of generating an immune response to PSA (Prostate Specific Antigen), but differ as to the steps and means of generating the response. Groups I entails the introduction of: a pox viral vectors that encode PSA ; the addition of PSA or a cytotoxic T-cell eliciting epitope; followed by the addition of another pox viral vector encoding PSA. Group II entails the introduction of: PSA or cytotoxic T-cell eliciting epitope; addition of PSA or a cytotoxic T-cell eliciting epitope; followed by a pox viral vector encoding PSA. Group III entails contacting the host with cytotoxic T-cell eliciting epitope. All these methods are different with respect to modes of operation.

3. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II or III, restriction for examination purposes as indicated is proper.

4. Claims 6-10 and 12 are generic to a plurality of disclosed patentably distinct species comprising suipox, avipox (fowlpox, canary pox, pigeon pox), capripox, orthopox, and adjuvants (RIBI Detox, QS21, incomplete Freund's). Because these

species are capable of being combined in a multitude of combinations, a single species must be elected from the pox viruses, namely suipox, avipox, capripox, orthopox, and adjuvants. If avipox is elected, applicant must elect one of fowlpox, canary pox, or pigeon pox. In regards to adjuvants, a single species must be elected from RIBI Detox, QS21 or incomplete Freund's adjuvants. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

GEETHA P. BANSAL
PRIMARY EXAMINER

Christopher Yaen
Art Unit 1642
December 14, 2001